



The European coordinating committee for the integration of ongoing Coordination Actions (CAs) related to clinical, virological and epidemiological HIV research (CASCADE, EuroHIVResistance, EuroSIDA, PENTA/ECS, COHERE)

EUROCOORD-CHAIN - joint project on transmitted drug resistance

Impact of the virus variability in antiretroviral-naïve patients on response to initial combination Antiretroviral Treatment (cART)

Version 1.11 Standard Operating Procedure for data transfer

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1. Introduction to the EuroCOORD-CHAIN SOP

This document provides guidance on the preparation of data files for the first data transfer for the EuroCOORD-CHAIN Collaboration, as a pilot project to show the potential of this collaboration. The EuroCOORD-CHAIN structure, to the extent possible, conforms to the HICDEP (HIV Cohorts Data Exchange protocol). The latest version of HICDEP is available at the CHIP website: www.cphiv.dk/HICDEP.pdf. Changes and additions are always part of the on-going process for projects that extend over time and EuroCOORD-CHAIN is no exception.

Thank you very much for your contribution to this collaborative project!

2. First joint project of EuroCOORD: “Impact of the virus variability in antiretroviral-naïve patients on response to initial combination Antiretroviral Treatment (cART)”

Among the agreed milestones of EuroCOORD (the four EU-funded Coordinated Actions: CASCADE, EuroHIVResistance, EuroSIDA, PENTA/ECS, and COHERE) is the identification of a collaborative pilot project “based on relevant available data among most, and preferably all, five partners”.

This project is part of the EU-funded CHAIN infrastructure project-WP3 (FP7 call on HIV Resistance).

3. Objectives

3.1. EuroCoord-CHAIN project

The objective of the project is to compare virological, immunological and clinical outcome up to 12-16 months following initiation of cART, according to markers of virus variability (specific mutations, subtypes), and relevant to the drugs in the regimen.

3.2. HCV project

The objectives of the project are to describe:

- the characteristics of HIV-infected patients who received HCV treatment,
- the short term effects of (PEG) IFN on absolute CD4 cell counts and percent CD4, stratified by CD4 cell counts at time of treatment initiation,
- the short term effects of (PEG) IFN treatment on the HIV and HCV virologic trajectories,
- the long term effects of (PEG) IFN treatment on the occurrence of AIDS defining events as well as non-AIDS defining events in patients with HCV co-infection,
- the long term effects of (PEG) IFN treatment on all-cause and cause specific mortality in patients with HCV co-infection
- to evaluate the effect of ABC containing regimen on the response to HCV treatment in HIV/HCV coinfecting patients.
- To assess incidence and risk factor for HCC in HIV infected persons
- To identify cases of HCC occurred in HIV infected patients and establish a registry with basic informations on treatment, survival and HIV related predictors of survival
- To assess the rate of treatment (OLT, surgery, other) and post treatment survival
- identify the rates of SVR in cohorts of HIV infected persons
- identify the determinants of SVR in HIV coinfecting patients who underwent anti HCV treatment with minimal data available (HCV genotype, treatment schedule)
- assess the impact of sustained virologic response (SVR) on overall survival, liver mortality, liver decompensation and occurrence of Hepato Cellular Carcinoma (HCC) .

4. Timing of the 1st merger

For the EuroCOORD-CHAIN data mergers, each cohort/collaboration will be responsible for gathering and computerizing its own data; subsequently it will then be electronically merged into the respective Coordinating Centres of each network and ultimately merged as the EuroCOORD-CHAIN main database. Therefore, each network Coordinating Centre will be responsible for distributing this SOP to their affiliated cohorts.

The deadline for data submission by cohorts to each Network Coordinating Centre for this merger is **1 June 2009** (do send it earlier if possible). During 6 weeks after the submission of data, i.e until around **15 July 2009**, each Network Coordinating Centre will send out error and discrepancy information in the form of discrepancy report. Each Network Coordinating Centre will spend the next 4 weeks processing cohorts' response to these reports and working closely with cohorts to clean the data. The cleaning of the data should be completed by **15 August 2009**.

5. Eligibility criteria for patients

5.1. EuroCoord-CHAIN project

Please include **all patients** regardless of age:

- **with at least one genotypic test before exposure to any antiretroviral treatment**
- with a minimal core data available as described below

Additionally, children and young people who were exposed to antiretrovirals for the prevention of mother-to-child transmission (either pre- or post-natally) must have:

- at least one resistance test before exposure to cART (defined as a regimen with at least 3 antiretroviral drugs)

Among this study population, a sub-population will be defined as:

- patients who have **started cART**, defined as a regimen with at least 3 antiretroviral drugs
- **since 1 January 1998**
- while **being antiretroviral naïve**

5.2. HCV project

Please include all patients regardless of age (adults and children):

- **with at least one test regarding HCV infection**
- who have **started cART**, defined as a regimen with at least 3 antiretroviral
- **since 1 January 1998**
- while **being antiretroviral naïve**

5.3. Both projects

If you are going to participate to both projects, please pay specific attention to eligibility criteria of each project.

6. Justification of data needed in narrative and HICDEP formats

Please submit the data you have for each selected patient. Regarding the EuroCoord-CHAIN project, please submit all measurements taken during at least the 12 months after initiation of cART.

6.1. List of minimal data items required

6.1.1. Core data

- Demographic characteristics : patient identifier, year of birth, gender, HIV risk transmission group
- HIV-test results : first positive or date of seroconversion and last negative HIV serology, where available
- Antiretroviral therapy : individual drugs used (start and stop dates), including for prevention of mother-to-child transmission
- All plasma HIV-1 RNA levels and dates (incl. detection limit, if undetectable)
- All CD4 cell counts (and percent CD4 and/or total lymphocytes, among children in any case and among adults if available) and dates
- Complete clinical history: AIDS-defining events according to the CDC and death, and cause of death if available
- Date of beginning of active follow-up (for patients who started being followed in a cohort at some point several months or years after being diagnosed) and all visit dates.

6.1.2. Antiretroviral drug resistance and HIV subtype

Genotypic test results at any time point prior to initial cART.

- Basic sample information: date and ID
 - background data on the resistance test:
 - date and time of sequencing
 - laboratory where the sequencing was performed
 - whether the lab participates in QA for genotyping
 - kit used
 - software and library (version) to deduce resistance/susceptibility
 - reference sequence used to which mutations has been identified
 - the subtype of the virus if that is known.
- Detailed resistance data in one of the following levels:
 - Level 1 (preferred): sequence data in nucleotides for the targeted enzymes: protease, reverse-transcriptase, (integrase, gp41 when available) etc.
 - Level 2 (secondary choice): list of point mutations numbered in relative position of the targeted enzyme in comparison to a reference, listing mixtures and insertions

Please do only report your data on one level – going from level 1 to 2 in order of preference.

6.1.3. List of variables not defined as minimal data items required but needed for consistency checks or analysis

- Date of enrolment into the cohort
- Full date of birth
- Nationality or region of origin of patient
- Ethnicity of patient
- Has the patient received antiretroviral treatment
- Has the patient been given an AIDS diagnosis. If yes, date of AIDS diagnosis
- Drop-out information
- Cross-cohort identification
- Reason for stopping treatment
- Viral assay used for HIV-1 RNA measurement
- Type if resistance test
- Start and stop position for a sequence

6.2. List of all variables according to HICDEP format

Variables/data needed	HICDEP table	HICDEP variables
Patient identifier	BAS	PATIENT, BIRTH_D, ENROL_D, GENDER, MODE, MODE_OTH, ORIGIN, ETHNIC, SEROCO_D, SEROCO_M, RECARD_Y, AIDS_Y, AIDS_D, ALCO_Y
Birth date		
Sex		
Mode of infection		
Region of origin		
Ethnicity		
HIV-test results		
Date of enrolment into the cohort		
Has the patient received ART?		
Has the patient been given an AIDS diagnosis. If yes, date of AIDS diagnosis		
Has the patient ever abused alcohol?		
Death	LTFU	PATIENT, DROP_Y, DROP_D, DROP_RS, DEATH_Y, DEATH_D, DEATH_R1, DEATH_RC1, DEATH_R2, DEATH_RC2
Patient	OVERLAP	PATIENT, COHORT, PAT_OTH, COH_OTH
Cohort		
Visit dates and visit related measurements and status	VIS	PATIENT, VIS_D, WEIGH, GAIN_Y, LOSS_Y, HEIGH
Antiretroviral therapy	ART	PATIENT, ART_ID, ART_SD, ART_ED, ART_RS
Reasons for stopping regimen		
Other medication	MED	PATIENT, MED_ID, MED_SD, MED_ED
AIDS defining events	DIS	PATIENT, DIS_ID, DIS_D, DIS_WD
Laboratory values	LAB	PATIENT, LAB_ID, LAB_FA, LAB_ST, LAB_D, LAB_V, LAB_U
CD4 cell counts and %	LAB_CD4	PATIENT, CD4_D, CD4_V, CD4_U
Plasma HIV-1 RNA	LAB_RNA	PATIENT, RNA_D, RNA_V, RNA_L, RNA_T
Viro-/serology tests	LAB_VIRO	PATIENT, VS_ID, VS_D, VS_R, VS_V, VS_U
Resistance test, background information	LAB_RES	PATIENT, SAMP_ID, SAMPLE_D, SEQ_DT, LAB, TESTTYPE, KIT, SOFTWARE, LIBRARY, REFSEQ, SUBTYPE
Sequence data in nucleotide format	LAB_RES_LVL_1	SAMP_ID, SEQTYPE, SEQ_STAR, SEQ_STOP, SEQ_NUC
Amino acid mutations	LAB_RES_LVL_2	SAMP_ID, GENE, AA_POS, AA_POS_SUB, AA_FOUND_1, AA_FOUND_2, AA_FOUND_3, AA_FOUND_4

See Section 12 "Details of Variables needed (HICDEP format)" for more details.

7. EuroCOORD data sections

7.1. Demographic, Clinical and Background Information (BAS)

Each patient should appear once in this table.

Please make sure that the enrolment date, ENROL_D, is the date that the patient enrolled in the local cohort.

If an AIDS event has been diagnosed, please report the date of AIDS diagnosis (AIDS_D).

The BAS table in the Appendix describes the coding of these variables in more detail.

Please submit the date of 1st HIV-1 positive test and provide the correct code in SEROCO_M (code = 4). In case that you do not have the date for the 1st HIV-1 positive test please submit the date of seroconversion in SEROCO_D and indicate the correct code in SEROCO_M to specify the source of this date.

7.2. Death and drop-out (LTFU)

All of the death and drop-out variables are incorporated in this table.

A patient is considered as drop-out if he/she has left the cohort, withdrawn consent, or if there is no new information on the patient during the preceding twelve months. Patients without a visit date, death date or drop-out date will be considered lost to follow-up.

When cohorts have recorded the “underlying” cause of death, they should only report the underlying cause of death in the variable “DEATH-R1” and “DEATH-RC1”. The underlying cause of death is defined by the disease or injury which initiated the train of morbid events leading to death (International Classification of Diseases-10th revision).

When cohorts have recorded cause(s) of death but cannot differentiate between the “immediate”, “contributing” or “underlying” cause(s), they should report all available data “DEATH-R1” and “DEATH-R2”. When submitting, each cohort should identify whether they have recorded the underlying cause of death or not in the variables “DEATH-RC1” and “DEATH-RC2”.

The LTFU table in the Appendix describes the coding of these variables in more detail.

7.3. Cross-cohort identification (OVERLAP)

Please submit the OVERLAP: Cross-Cohort Identification table even if you don't have patients participating in other EuroCOORD-CHAIN cohorts (in this case, leave the table empty).

Patients who are known to be in other cohorts participating in EuroCOORD-CHAIN should be entered in this table, once for each cohort. Two fields are provided for this information: The COH_OTH field contains a 20-character name identifying the other cohort and the PAT_OTH field is for the unique patient identifier used in this cohort.

Please note that the data submitted is requested to be on all patients that fulfil the inclusion criteria. Do not remove patient data for which you know overlaps with other patients in other cohorts!

An algorithm has been developed to identify overlaps between cohorts based on similarity between patient characteristics (probalistic linkage). Further optimisation and validation is however needed. For this to be done we need as many known overlapping

patients between cohorts and the detailed data as possible. Identified overlaps NOT listed in the OVERLAP file will be queried back to the cohorts for verification.

COHERE RCCs has a set of agreements registered between overlapping cohorts and hospital clinics that participate in more than one cohort as to who will include their data into the analysis. Based on these agreements the RCCs will perform inclusion and exclusion of these patients centrally at the RCCs.

A central registry of overlaps and inclusion/exclusion rules on patient, site, country and cohort level will be maintained by the two RCCs. Following this merger the algorithm will be presented, published and thereby made publicly available for other collaborations to use.

7.4. Basic follow-up/visit related data (VIS)

See the VIS table in the Appendix for details.

7.5. Antiretroviral drug variables (ART)

Each antiretroviral treatment is identified by its Anatomical Therapeutic Chemical (ATC) code, which can be up to 12 characters. If the patient has been given ART, enter the proper ATC code in the ART_ID field followed by ART_SD (start date) and ART_ED (stop date).

The ART table in the Appendix describes the coding of these variables in more detail.

7.6 Other medication (MED)

7.7. AIDS-defining opportunistic infections (DIS)

All DIS_ID (code to identify the event) and DIS_D (date of AIDS-defining opportunistic events) should be reported.

See the DIS table in the Appendix for details.

7.8 Laboratory values – LAB (LAB)

See the LAB table in the appendix for details.

7.9. Laboratory values – CD4 (LAB_CD4)

See the LAB_CD4 table in the Appendix for details.

7.10. Laboratory values- HIV-1 RNA (LAB_RNA)

See the LAB_RNA table in the Appendix for details.

The RNA_V (HIV-RNA measurement value (copies/ml)) should be coded as -1 only if the value is strictly inferior to the RNA_L (lower limit of HIV-RNA assay).

7.11 Viro-/serology tests – HIV, HBV, HCV etc (LAB_VIRO)

See the LAB_VIRO table in the appendix for details.

7.12. Background information on resistance tests (LAB_RES)

In this table any relevant information about the actual resistance test should be provided, sectioned into sample information:

- SAMP_ID: sample id – should be unique for all samples in the cohort,

- SAMPLE_D: date the sample was drawn,
- SEQ_DT: please provide date and time for sequencing if the result obtained is a genotypic test
- LAB: text to give name of the laboratory,
- TESTTYPE: either genotype or phenotype – or both at the same time,
- KIT: name of the commercial kit used for the sequencing/phenotype test or if in house please specify this.
- SOFTWARE and LIBRARY to provide information on the software and the library/version that was used to get the resistance scores if that is provided in LAB_RES_LVL_3.
- REFSEQ to inform which ref. Sequence was use in the phenotype test or which sequence was used as wildtype reference in the genotype tests.
- Subtype should, if available, be reported in SUBTYPE.

7.13. Level 1: Nucleotide sequence data (LAB_RES_LVL_1)

This is the preferred level at which resistance tests should be reported if the full sequence is available, please dissect the sequence data into the genes for the enzymes that are targeted with treatment: protease, reverse-transcriptase etc. If available please also state start and end of the sequencing attempt – hence primers used for protease sequences often cut-off the first 9 nucleotides, for RT this is often the first ~112 nucleotides.

7.14. Level 2: Amino acid mutations (LAB_RES_LVL_2)

List all identified mutations here that are recorded for the test, do not submit data here if the full sequence is available nor if the test was a phenotype test. The format allows for submission of mixtures/ambiguous nucleotides that code for more than one amino acid. Up to 4 fields are available for this – in need of more please add additional fields. Insertions should be coded with a sub-position variable: a, b, c etc – please see example in 10.1.4. Deletions are to be added with a position and no amino acid code or a “-“ in AA_FOUND_1 (and blank for the other AA_FIELD_# variables)

8. EuroCOORD-CHAIN data format

Please submit your data using the HICDEP formats described in the tables in the section 11. The HICDEP format is based on a relational structure and currently incorporates 15 data tables and numerous lookup-tables for the codes.

8.1. Blank values

When a variable is not applicable or missing and there is no code for the reason, then leave it blank. The cohort validation consistency check programs will detect and report back on any invalid blanks i.e. when a response is required or when there is a code you could use such as "unknown" or "unavailable" or "missing"

8.2. Unknown values

The category “unknown” indicates that the information needed is unknown or purposely left as missing. The codes 9, 99 and 999 are used to designate this category. Please see the tables in the Appendix for the specific coding.

The date of 1911-11-11 is to be used, whenever the use of a drug, a treatment episode etc, is known to have occurred but the date is unknown. Similarly, for other types of variables, there is most often “yes/no” question, followed by the “date” question (for example: “Has the patient an AIDS diagnosis?” and then: “If yes, date of AIDS diagnosis”). For these types of questions, if the event is known to have occurred but the date is unknown, code the date as: 1911-11-11. Then the EuroCOORD-CHAIN validation programs will detect a “yes AIDS diagnosis” – “unknown date of AIDS diagnosis”. If the only information available regarding a date is the year, then it should be entered as July 1, XXXX (XXXX-07-01). If the month and the year are given, the date should be entered with the day being the 15th.

9. Data file transfers

Cohorts will submit their data using Access (version 97 or 2000), SAS (version 8 or 9), STATA (version 6), ASCII semicolon separate files or XML format. For paediatric cohorts, please submit your data using Access or Excel. Network Coordinating Centres will take care of the final transformation from cohorts’ preferred data format with StatTransfer.

For security purposes, cohort data files to be transferred to their Network Coordinating Centres and between the five Network Coordinating Centres will be encrypted and compressed with ZIP archive using the AES encryption algorithm. One of the Network Coordinating Centres will perform the merger of the databases prepared by the five Network Coordinating Centres. The encryption password (minimum 10 characters long, including upper/lowercase, numbers and special characters) will be communicated to the data manager at the Network Coordinating Centre performing the overall merger by fax or by telephone. These zip-files can be uploaded onto the servers of this coordinating centre using the secure file transfer protocol (ftps) or send on a CD-ROM by registered mail.

10. Error and discrepancy reporting

Within six weeks of data submission, each Network Coordinating Centre will e-mail a report to the cohort data managers in order for them to check and correct their data and to replace “missing” values.

The cohort data managers should enter the corrected data into their own database and then send the revised tables to each Network Coordinating Centre. These revised tables will then be re-checked and then, if there are no further problems, added to the rest of the cohort’s data.

11. National Regulations

As the EuroCOORD-CHAIN collaboration will be an academic collaboration between an anticipated number of 800 centres in over 30 European countries, it is the responsibility of investigator/sponsor of each cohort to follow current national regulations, regarding data extraction and data transfer.

12. Details of Variables needed (HICDEP format)

12.1. Variables needed for the research analysis (HICDEP format)

12.1.1. Basic clinical, background and demographic information (BAS file)

Table 1 below details the baseline data that should be included in BAS file.

Projects: CHAIN and HCV

Table 1 – Variables to be included in BAS file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
CENTER	Character	Code for Clinic/Centre/Hospital where patient is seen.
BIRTH_D	Date (for example yyyy-mm-dd)	Birth date
FRSVIS_D	Date (for example yyyy-mm-dd)	First seen at clinic
ENROL_D	Date (for example yyyy-mm-dd)	Date of enrolment into the cohort
GENDER	Numeric with codes : 1 = Male 2 = Female 9 = Unknown	Gender/Sex
HEIGH	Numeric (metric - meters): 999=Unknown	Height of patient at visit/most current – use HEIGHT variable in table VIS for children also.
MODE	Numeric with codes : 1 = homo/bisexual 2 = injecting drug user 3 = homo/bisexual and injecting drug user 4 = haemophiliac 5 = transfusion, non-haemophilia related 6 = heterosexual contact 7 = heterosexual contact and injecting drug user 8 = perinatal 90 = other (specify) 99 = unknown	Mode of infection
MODE_OTH	Characters	Mode of infection OTHER
ORIGIN	Numeric with codes: 10 = Africa 11 = Northern Africa 12 = Sub-Saharan Africa 20 = Asia 30 = Oceania (not Australia) 40 = Australia & New Zealand 50 = Americas 51 = North America 52 = Central & South America 60 = Middle East 70 = Europe 71 = Western Europe 72 = Eastern Europe 99 = Unknown	Nationality or region of origin of patient
ETHNIC	Numeric with codes: 10 = White 20 = Black 21 = Black African 22 = Black Caribbean	Ethnicity of patient

Name	Format and definition	Description
	30 = Hispanic 40 = Asian 50 = American 60 = Indigenous 1020 = White/Black 1040 = White/Asian 2030 = Black/Hispanic 3040 = Hispanic/Asian 102040 = White/Black/Asian 97 = other 98 = Prohibited 99 = Unknown	
SEROCO_D	Date (for example yyyy-mm-dd)	Date of seroconversion or date of 1 st HIV diagnosis
SEROCO_M	Numeric with codes : 1=midpoint between last neg. and first pos. HIV-1 test 2=lab evidence of seroconversion 3=seroconversion illness 4=first pos HIV-1 test 9=other	Source of the SEROCO_D
RECART_Y	Numeric: 0=No 1=Yes 9 = Unknown	Has the patient received antiretroviral treatment?
AIDS_Y	Numeric with codes : 0 = No 1 = Yes 9 = Unknown	Has the patient been given an AIDS diagnosis?
AIDS_D	Date (for example yyyy-mm-dd)	If yes, date of AIDS diagnosis
ALCO_Y*	Numeric with codes : 0 = No 1 = Yes 9 = Unknown	Has the patient ever been abusing alcohol?

Example :

PATIENT	BIRTH_D	FRSVIS_D	ENROL_D	GENDER
991	1928-07-08	1998-11-15	1998-12-09	1
992	1949-05-26	2001-06-29	2001-06-29	2
993	1937-09-07	1999-09-07	2000-06-02	1

HEIGH	MODE	MODE_OTH	ORIGIN	ETHNIC
1,76	6		71	10
1,95	6		71	10
1,78	1		12	20

SEROCO_D	SEROCO_M	RECART_Y	AIDS_Y	AIDS_D	ALCO_Y
1998-07-21	3	1	0	1999-08-12	0
2000-04-12	3	1	1	1999-09-13	0
1999-09-30	3	1	0		1

* Additional field according to HICDEP 1.5, needed for the HCV project

12.1.2. Death and drop-out (LTFU file)

Table 2 below details the information to be included in LTFU file.

Projects: CHAIN and HCV

Table 2 - Variables to be included in LTFU file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
DROP_Y	Numeric with codes: 0 = No 1 = Yes	Has the patient dropped out?
DROP_D	Date (for example yyyy-mm-dd)	If yes, date of last visit
DROP_RS	Numeric with codes: 0 = Patient was not infected (mainly for children) 1 = Patient lost to follow-up / not known to be dead 2 = Patient has not had visit within required amount of time 2.1 = Patient did not respond to several invitations 3 = Patient moved away 3.1 = Patient moved to another country 4 = Patient moved and is followed by another centre 4.1 = Paediatric patient transferred to adult care 5 = Patients decision 5.1 = Patients caretaker wanted to discontinue (for children) 6 = Consent withdrawn* 7 = Incarceration/jail 8 = Institutionalisation (drug treatment, psychological ...etc.) 9 = Other	If yes, reason for drop
DEATH_Y	Numeric with codes: 0 = No 1 = Yes	Has the patient died?
DEATH_D	Date (for example yyyy-mm-dd)	Date of death
DEATH_R1	Numeric with codes : 1 = Myocardial infarction 2 = Stroke 3 = Other cardiovascular diseases 4 = Symptoms caused by mitochondrial toxicity 4.1 = Lactic acidosis 5 = Complications due to diabetes mellitus 6 = Pancreatitis 7 = Complications due to hepatitis 7.1 = Hepatitis related 7.2 = Liver failure not related to hepatitis or mitochondrial toxicity 8 = HIV-related 8.1 = AIDS defining event 8.2 = Invasive bacterial infection 9 = Renal failure 10 = Bleeding (haemophilia) 20 = non-AIDS defining cancer 50 = sudden infant death 51 = neonatal death (including prematurity/ other complications) 55 = child abuse 90 = Other 91 = Suicide 92 = Drug overdose 93 = accident 99 = unknown, fatal case with no information	Cause of death
DEATH_RC1	Character with codes: I = Immediate cause U = Underlying cause/condition	Coding of causal relation of the code given in DEATH_R1 to

Name	Format and definition	Description
	C = Contributing cause N = Not available	the death
DEATH_R2	Numeric with codes : 1 = Myocardial infarction 2 = Stroke 3 = Other cardiovascular diseases 4 = Symptoms caused by mitochondrial toxicity 4.1 = Lactic acidosis 5 = Complications due to diabetes mellitus 6 = Pancreatitis 7 = Complications due to hepatitis 7.1 = Hepatitis related 7.2 = Liver failure not related to hepatitis or mitochondrial toxicity 8 = HIV-related 8.1 = AIDS defining event 8.2 = Invasive bacterial infection 9 = Renal failure 10 = Bleeding (haemophilia) 20 = non-AIDS defining cancer 50 = sudden infant death 51 = neonatal death (including prematurity/ other complications) 55 = child abuse 90 = Other 91 = Suicide 92 = Drug overdose 93 = accident 99 = unknown, fatal case with no information	Cause of death
DEATH_RC2	Character with codes: I = Immediate cause U = Underlying cause/condition C = Contributing cause N = Not available	Coding of causal relation of the code given in DEATH_R2 to the death

Example :

PATIENT	DROP_Y	DROP_D	DROP_RS	DEATH_Y	DEATH_D	DEATH_R1	DEATH_RC1	DEATH_R2	DEATH_RC2
991	0			0					
992	1	2002-09-13	1	0					
993	0			1	2002-10-14	8.1	I		

IMPORTANT: Please append as many DEATH_R# and DEATH_R#_T columns as you need to submit all your registered causes of death.

12.1.3. Cross-cohort identification (OVERLAP file)

Table 3 below details the information to be included in OVERLAP file.

Projects: CHAIN and HCV

Table 3 - Variables to be included in OVERLAP file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
COHORT	Character	Code/name of the cohort
PAT_OTH	Character	Unique patient identifier in other cohorts
COH_OTH	Character	Name of the cohort

Example :

PATIENT	COHORT	PAT_OTH	COH_OTH
991	FHDH	712	COPILOTE

12.1.4. Basic follow-up/visit related data (VIS file)

Table 4 below details the information to be included in VIS file.

Projects: CHAIN and HCV

Table 4 - Variables to be included in VIS file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
VIS_D	Date (for example yyyy-mm-dd)	Date of patient visit
WEIGH	Numeric (metric - kilograms) 999=Unknown	Weight of the patient at visit
LOSS_Y*	Numeric with codes : 0 = No 1 = Yes 9 = Unknown	Is the patient experiencing loss of fat from extremities, buttocks or face?
GAIN_Y*	Numeric with codes : 0 = No 1 = Yes 9 = Unknown	Is the patient gaining fat in the abdomen, neck, breast or other defined locations?
HEIGH#	Numeric (metric - meters): 999=Unknown	Height of patient at visit – relevant for children only – use HEIGHT variable in table BAS for adults.

Example :

PATIENT	VIS_D	WEIGH	LOSS_Y	GAIN_Y	HEIGH
991	1998-12-14	76	1	1	
991	1999-04-25	80.5	1	1	
991	2000-05-02	81	1	1	
991	2001-03-21	82	0	1	
991	2002-02-11	90	0	1	
991	2003-03-14	85	0	0	
991	2004-01-05	86	0	0	
992	2001-07-14	100	0	0	
992	2002-09-13	87	0	0	
993	2000-08-12	65	0	0	
993	2001-09-03	999	0	0	
993	2002-08-16	75	1	1	

* Mandatory fields according to HICDEP 1.5 format, may be left blank for this merger

Additional field according to HICDEP 1.5, needed for children only

12.1.5. Antiretroviral drug variables (ART file)

Table 5 below details the data on antiretroviral regimens that should be included in the ART file.

Projects: CHAIN and HCV

Table 5 – Variables to be included in ART file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
ART_ID	Character with codes: J05A=ART unspecified Protease inhibitors J05AE=PI unspecified J05AE01=Saquinavir (gel, not specified) J05AE01-SQH=Saquinavir hard gel (INVIRASE) J05AE01-SQS=Saquinavir soft gel (FORTOVASE) J05AE02=Indinavir (CRIXIVAN) J05AE03=Ritonavir (NORVIR) J05AE03-H=Ritonavir high dose (NORVIR) J05AE03-L=Ritonavir low dose (NORVIR) J05AE04=Nelfinavir (VIRACEPT) J05AE05=Amprenavir (AGENERASE) J05AE06=Lopinavir/Ritonavir (Kaletra) J05AE07=Fos-amprenavir (Telzir, Lexiva) J05AE08=Atazanavir (Reyataz) J05AE09=Tipranavir (Aptivus) J05AE10=Darunavir (TMC-114, Prezista) J05AE-MOZ=Mozenavir (DMP-450) Nucleoside and nucleotide reverse transcriptase inhibitors J05AF=NRTI unspecified J05AF01=Zidovudine (AZT, RETROVIR) J05AF02=Didanosine (ddI) (VIDEX) J05AF03=Zalcitabine (ddC) (HIVID) J05AF04=Stavudine (d4T) (ZERIT) J05AF05=Lamivudine (3TC, EPIVIR) J05AF06=Abacavir (1592U89) (ZIAGEN) J05AF07=Tenofovir (ViiREAD) J05AF08=Adefovir (PREVEON) J05AF09=Emtricitabine J05AF10=Entecavir J05AF11=Telbivudine J05AF-ALO=Alovudine J05AF-AMD=Amdoxovir (DADP) J05AF-FOZ=Fozivudine tidoxi J05AF-LDN=Lodanosine (trialdrug) J05AF-RVT=Reverset Non-nucleoside reverse transcriptase inhibitors J05AG=NNRTI unspecified J05AG01=Nevirapine (VIRAMUN) J05AG02=Delavirdine (U-90152) (RESCRIPTOR) J05AG03=Efavirenz (DMP-266) (STOCRIN, SUSTIVA) J05AG-CPV=Capravirine J05AG-DPC083=DPC 083 J05AG-DPC961=DPC 961 J05AG-EMV=Emivirine (MKC442) J05AG-ETV=Etravirine (TMC 125) J05AG-LOV=Loviride J05AG-RPV=Rilpivirine (TMC-278) Combination drugs J05AR01=Combivir (Zidovudine/Lamivudine) J05AR02=Kivexa (Lamivudine/Abacavir)	Code representing the antiretroviral treatment

Name	Format and definition	Description
ART_ID	J05AR03=Truvada (Tenofovir/Emtricitabine) J05AR04=Trizivir (Zidovudine/Lamivudine/Abacavir) J05AR05=Douvir-N (Zidovudine/Lamivudine/Nevirapine) J05AR06=Atripla (Emtricitabine/Tenofovir/Efavirenz) Integrase Inhibitors J05AX-EVG=Elvitegravir (Gilead) J05AX08=Raltegravir (Merck) Maturation inhibitors J05A-BEV=Beviramat Fusion inhibitors J05AX07=Enfuvirtide (Fuzeon, T-20) J05AX09=Maraviroc (Pfizer) J05AX-VIC=Vicriviroc (Schering) Other L01XX05=Hydroxyurea/Hydroxycarbamid (Litalir) J05A-PBT=Participant in Blinded Trial	Code representing the antiretroviral treatment
ART_SD	Date (for example yyyy-mm-dd)	Date of initiation of treatment
ART_ED	Date (for example yyyy-mm-dd)	Date of stopping treatment
ART_RS	Numeric with codes: 1 = Treatment failure (i.e. virological, immunological, and/or clinical failure) 1.1 = Virological failure 1.2 = Partial virological failure 1.3 = Immunological failure – CD4 drop 1.4 = Clinical progression 2 = Abnormal fat redistribution 3 = Concern of cardiovascular disease 3.1 = Dyslipidaemia 3.2 = Cardiovascular disease 4 = Hypersensitivity reaction 5 = Toxicity, predominantly from abdomen/G-I tract 5.1 = Toxicity – GI tract 5.2 = Toxicity – Liver 5.3 = Toxicity – Pancreas 6 = Toxicity, predominantly from nervous system 7 = Toxicity, predominantly from kidneys 8 = Toxicity, predominantly from endocrine system 8.1 = Diabetes 9 = Haematological toxicity (anaemia...) 10 = Hyperlactataemie/lactic acidosis 70 = Pregnancy – toxicity concerns 75 = Pregnancy – prevention of mother to child transmission 76 = Post-partum prophylaxis 77 = Dose change for height/ weight 88 = Death 90 = Side effects – any of the above but unspecified 90.1 = Co morbidity 91 = Toxicity, not mentioned above 92 = Availability of more effective treatment (not specifically failure or side effect) 92.1 = Simplified treatment available 92.2 = Treatment to complex 92.3 = Drug interaction 93 = Structured Treatment Interruption (STI) 93.1 = Structured Treatment Interruption (STI) – at high CD4 94 = Patient's wish/decision 94.1 = Non-compliance 95 = Physician's decision 97 = Study treatment 98 = Other causes 99 = Unknown	Reason for stopping treatment

Example:

PATIENT	ART_ID	ART_SD	ART_ED	ART_RS
991	J05AF08	2000-10-21	2000-12-12	1
991	J05AF04	2001-03-03		
991	J05AF02	2000-10-21		
992	J05AE02	2002-04-12	2002-05-18	3.1
992	J05AE03	2002-04-12	2002-05-18	3.1

12.1.6. Other medication – used for treatment or prophylaxis of OIs, treatment against HBV and HCV and immune-modulators (MED file)

Table 6 below details the baseline data that should be included in MED file.

Projects: HCV

Table 6 – Variables to be included in MED file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
MED_ID	Character with codes: J01AA08=Minocycline (MINOCIN) J01EA01=Trimethoprim (MONOTRIM) J01EC02=Sulfadiazine J01EE01=Sulfamethoxazole and trimethoprim (Bactrim) J01EE03=Sulfametrole and trimethoprim - Cosoltrime (MADERAN) J01EE=Cotrimoxazole - Comb. of sulfonamides and trimethoprim (BACTRIM, EUSAPRIM, NOPIL) J01FA09=Clarithromycine (KLACID) J01FA10=Azithomycine (ZITHROMAX) J01FF01=Clindamycine (DALACIN) J01GB06=Amikacine (AMIKINE) J01MA02=Ciprofloxacin (CIPROXINE, CILOXAN) J01MA12=Levofloxacin (TAVANIC) J01MA14=Moxifloxacin J01RA02=Cosoltrime (MADERAN) J02AA01=Amphotericin B (FUNGIZON) J02AB02=Ketoconazole J02AB=Imidazoles (DAKTARIN, NIZORAL, PEVARYL) J02AC01=Fluconazole (DIFLUCAN) J02AC02=Itraconazole (SPORANOX) J02AC03=Voriconazole J04AB02=Rifampin (RIMATICIN) J04AB04=Rifabutin (MYCOBUTIN) J04AC01=Isoniazide (RIMIFON) J04AK01=Pyrazinamide (PYRAZINAMID) J04AK02=Ethambutol (EMB, MYAMBUTOL) J04AM02=RIFATER J04BA01=Clofazimine (LAMPREN) J04BA02=Dapsone J05AB01=Aciclovir (ZIVORAX) J05AB04=Ribavirin J05AB06=Ganciclovir (CYMEVENE) J05AB09=Famciclovir J05AB11=Valaciclovir (VALTEX) J05AB12=Cidofovir (VISTIDE) J05AD01=Foscarnet (FOSCAVIR) L03AA02=G-CSF/Filgrastim (NEUPOGEN) L03AB-AL2=Peginterferon alfa-2a/alfa-2b (PEGINTRON, PEGASYS)* L03AB10=Peginterferon alfa-2b (PEGINTRON)* L03AB11=Peginterferon alfa-2a (PEGASYS)* L03AB=Interferons* L03AC-IL2=Interleukin 2 (PROLEUKIN) P01AX06=Atovaquone (WELLVONE, MEPRONE)	Code representing the drug, any missing code can be found at: http://www.whocc.no/atcddd/indexdatabase

* Relevant for the HCV project, table can be limited to only contain treatment records for these drugs

Table 6 (continued) – Variables to be included in MED file

Name	Format and definition	Description
MED_ID	P01BD01=Pyrimethamine (DARAPRIM) P01BD51=Pyrimethamine/Sulfadoxine (FANSIDAR) P01CB=Antimony compounds P01CX01=Pentamidine aerosol (PENTACARNET) V03AF03=Folate of calcium (LEUCOVORINE)	Code representing the drug, any missing code can be found at: http://www.whocc.no/atcddd/indexdatabase
MED_SD	Date (for example yyyy-mm-dd)	Date of initiation of treatment
MED_ED	Date (for example yyyy-mm-dd)	Date of stopping treatment

Example:

PATIENT	MED_ID	MED_SD	MED_ED
991	L03AC-IL2	2000-10-21	2000-12-12
991	J05AB04	2001-03-03	
991	J02AA01	2000-10-21	
992	J05AB12	2002-04-12	2002-05-18
992	J01EE	2002-04-12	2002-05-18

12.1.7. Opportunistic infections (DIS file)

Table 7 below details the data on AIDS-defining opportunistic events diagnosed during follow-up that should be included in DIS file.

Projects: CHAIN and HCV

Table 7 – Variables to be included in DIS file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
DIS_ID	Character with codes: DEM=AIDS dementia complex BCNE=Bacterial pneumonia, recurrent (>2 episodes within 1 year) CANO=Candidiasis, oesophageal, bronchi, trachea, or lungs COCC = <u>Coccidioidomycosis</u> , disseminated or extrapulmonary CRCO=Cryptococcosis, extrapulm. CRSP=Cryptosporidiosis (duration > 1 month) CMVR=Cytomegalovirus (CMV) chorioretinitis CMVO=CMV - other location HERP=Herpes simplex virus ulcers (duration > 1 month) or pneumonitis/esophagitis/bronchitis HIST=Histoplasmosis, extrapulm. or disseminated WAST=HIV Wasting Syndrome ISDI=Isosporiasis diarrhoea (duration > 1 month) LEIS=Leishmaniasis, visceral MCDI=Microsporidiosis diarrhoeas (dur. > 1 month) MC=Mycobact. avium complex (MAC) or Kanasii, extrapulm. MCP=Mycobact. tuberculosis pulm. MCX=Mycobact. tuberculosis extrapulm. MCPO=Mycobact. pulm., other MCXO=Mycobact. extrapulm., other MCO=Mycobact., other PCP=Pneumocystis carinii pneumonia (PCP) LEU=Progressive multifocal leucoencephalopathy SAM=Salmonella bacteriaemia (non-typhoid) (recurrent) TOX=Toxoplasmosis, brain FBLS=Focal Brain lesion KS=Kaposi Sarcoma HG=Hodgkins Lymphoma NHG=Non-Hodgkin Lymphoma - not specified NHGB=Non-Hodgkin Lymphoma - Burkitt (Classical or Atypical) NHGI=Non-Hodgkin Lymphoma - Diffuse large B-cell lymphoma (Immunoblastic or Centroblastic) NHGU=Non-Hodgkin Lymphoma - Unknown/other histology NHGP=Non-Hodgkin Lymphoma - Primary Brain Lymphoma CRVC=Cervical Cancer <hr/> Paediatric specific CDC stage C codes: SRBI=Serious recurrent/ multiple bacterial infections CMVP=Cytomegalovirus (CMV) disseminated with onset >1 month, paediatrics ENC=Encephalopathy	Code to identify opportunistic event
DIS_D	Date (for example yyyy-mm-dd)	Date of event
DIS_WD	Numeric with codes: 1=Definitive diagnosis 2=Presumptive diagnosis 3=Diagnosis from autopsy 4=Diagnosis from registry 9=Unknown/unavailable	Way/means of diagnosis

Name	Format and definition	Description
DIS_OTH	Character	Other location, only to be filled out if code alone is not sufficient

Example :

PATIENT	DIS_ID	DIS_D	DIS_WD	DIS_OTH
991	ISDI	2000-10-21	1	
991	SAM	1999-08-12	2	
991	TOX	2001-07-14	1	
992	PCP	1999-09-13	9	

12.1.8. Laboratory values (LAB files)

Table 8 below detail the laboratory data that should be included in LAB files.

Projects: HCV

Table 8 – Variables to be included in LAB file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
LAB_ID	Character with codes: ALB=Albumine ALT=Alanin-Aminotransferase AST=Aspartat aminotransferase BIL=Total Bilirubin GGT=gGT HAEM=Haemoglobin INR=Quick/INR PLT=Platelet count PTR=Prothrombin rate	Code representing the measurement
LAB_FA	Numeric with codes: 0=No 1=Yes 9=Unknown	Was the blood sample taken while fasting?
LAB_ST	Character with codes: WB=Whole Blood P=Plasma S=Serum	Specimen type
LAB_D	Date (for example yyyy-mm-dd)	Date of measurement
LAB_V	Numeric -1 = undetectable or detection limit as negative value	Value of measurement
LAB_U	Numeric with codes: 1=mmol/L 2=gm/L 3=gm/dL 4=mg/dL 5=IU/L (u/L) 6=mmol/L 7=INR 8=1E+9/L 9=1E+6/L 10=cells/ μ L 11=mkat/L	Unit of measurement

Example :

PATIENT	LAB_ID	LAB_FS	LAB_ST	LAB_D	LAB_V	LAB_U
991	ALB	9	P	1998-04-13		
991	ALT	0	P	1998-04-13		
991	ALT	1	P	1999-08-12		
991	BIL	1	P	2001-07-14		
991	INR	1	WB	2001-09-13		
992	PLT	0	P	2000-05-18		
992	ALB	0	P	2000-05-18		
992	INR	9	WB	2001-03-30		

12.1.9. Laboratory values (LAB_CD4 files)

Table 9 below detail the laboratory data that should be included in LAB_CD4 files.

Projects: CHAIN and HCV

Table 9 – Variables to be included in LAB_CD4 file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
CD4_D	Date (for example yyyy-mm-dd)	Date of measurement
CD4_V	Numeric -1 = undetectable or detection limit as negative value	Value of CD4 measurement
CD4_U*	Numeric with codes: 1 = cells/ μ l 2 = % 3 = total lymphocytes/ μ l	CD4 cell count, CD4 percent or total lymphocyte count

Example :

PATIENT	CD4_D	CD4_V	CD4_U
991	1998-04-13	15	1
991	1998-04-13	85	2
991	1999-08-12	50	1
991	2001-07-14	100	1
991	2001-09-13	140	1
992	2000-05-18	197	1
992	2000-05-18	46	2
992	2001-03-30	213	1

* Additional field according to HICDEP 1.5, needed here to capture data for children primarily

12.1.10. Laboratory values (LAB_RNA files)

Table 10 below detail the laboratory data that should be included in LAB_RNA files.

Projects: CHAIN and HCV

Table 10 – Variables to be included in LAB_RNA file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
RNA_D	Date (for example yyyy-mm-dd)	Date of measurement
RNA_V	Numeric -1 = undetectable/below level of detection or detection limit as negative value	HIV-RNA measurement value (copies/ml)
RNA_L	Numeric	Lower limit of HIV-RNA assay
RNA_T	Numeric with codes: 5 = Roche TaqMan 6 = Roche TaqMan/AmpliPrep v2.0 10 = Roche 1.0 15 = Roche 1.5 ultra-sensitive 19 = Any Roche (unspecified) 20 = NASBA 21 = NASBA ultra-sensitive 29 = Any NASBA (unspecified) 31 = Chiron b-DNA 1.0 32 = Chiron b-DNA 2.0 33 = Chiron b-DNA 3.0 39 = Any Chiron (unspecified) 40 = Abbott ultra-sensitive 41 = Abbott LCx 50 = Monitor 1.0 51 = Monitor 1.0 ultra-sensitive 55 = Monitor 1.5 56 = Monitor 1.5 ultra-sensitive 59 = Monitor unspecified 65 = Cobas 1.5 66 = Cobas 1.5 ultra-sensitive 90 = Other 99 = Unknown	IF AVAILABLE, what type of viral assay was used for this measurement?
RNA_UL*	Numeric	Upper limit of HIV-RNA assay

Example :

PATIENT	RNA_D	RNA_V	RNA_L	RNA_UL	RNA_T
991	1998-04-13	12586	50		51
991	1999-08-12	4623	50		51
991	2001-07-14	200	50		51
991	2001-09-13	742	50		51
992	2000-05-18	500	50		15
992	2001-03-30	50	50		15
992	2002-01-14	-1	50		15

* Additional field according to HICDEP 1.5, by standard part of COHERE mergers

12.1.11. Viro-/serology tests (LAB_VIRO file)

Table 11 below detail the viro-/serology data that should be included in LAB_VIRO file.

Projects: CHAIN (for HIV-1 and HIV-2 results) and HCV

Table 11 – Variables to be included in LAB_VIRO file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort patient ID). Unique and anonymous
VS_ID	HBV=Marker for hepatitis B infection - test unknown HBVAC=HBV IgG antibody (core, HBcIgG) HBVAE=HBV antibody (envelope) HBVAS=HBV antibody (surface, HBsAb) HBVD=HBV-dna HBVGE=HBV antigen (envelope, HBeAG) HBVGS=HBV antigen (surface, HBsAg) HCV=Marker for hepatitis C infection - test unknown HCVA=HCV antibody IgG ¹ HCVR=HCV-rna HDVA=Hepatitis delta antibody HIV-1=HIV-1 test HIV-2=HIV-2 test	Code to identify viro-/serology test
VS_D	Date (for example yyyy-mm-dd)	Date of measurement
VS_R	Numeric 0= negative 1= positive 9= unknown/borderline	Result of test
VS_V	Numeric -1 = undetectable/below level of detection or detection limit as negative value	Measurement value (where relevant)
VS_U	Numeric with codes: 1=copies/mL 2=IU/mL 3=Geq (millions of genome equivalent)	Unit of measurement (where relevant) please communicate if unit of relevance is missing

¹ two step test: Screening with EIA, and confirmation by testing for a panel of specific antibodies (recombinant immunoblot assay): Only patients with a positive screening and confirmation test should be coded as positive

VS_LL*	Numeric	IF AVAILABLE, Lower Limit of assay
VS_UL*	Numeric	IF AVAILABLE, Upper Limit of assay
VS_T*	Numeric with codes: 1=Roche qualitative (Amplicor) [HCV and HBV] 2=Roche quantitative test for HBV (Cobas Amplicor HBV monitor) 3=Bayer Bdna quantitative [HCV] 4=Bayer Bdna quantitative [HBV] 5=Roche Taqman 9=Other	IF AVAILABLE, What type of ASSAY was used for this measurement?

Example:

PATIENT	VS_ID	VS_D	VS_R	VS_V	VS_U	VS_LL	VS_UL	VS_T
991	TOXA	1998-04-13	0					
991	CMVA	1998-04-13	1					
991	HCVA	1999-08-12	0					
991	HCVR	2001-07-14	1	100000000	1	617		1
991	HBVD	2001-09-13	1	38000	2	617		1
992	HBV	2000-05-18	0					
992	HCV	2000-05-18						
992	CMVA	2001-03-30	1					

* Mandatory fields according to HICDEP 1.5 format, may be left blank for this merger is unavailable

12.1.12. Main resistance table (LAB_RES file)

Table 12 below details the background data for the resistance test that should be included in LAB_RES file.

Projects: CHAIN and HCV (for HCV subtype)

Table 12 – Variables to be included in LAB_RES file

Name	Format and definition	Description
PATIENT	Character (or numeric if possible)	Code to identify patient (Cohort Patient ID)
SAMP_ID	Character (or numeric if possible)	The assigned UNIQUE sample ID
SAMPLE_D	Date (for example yyyy-mm-dd)	Date of the actual sample taken (NOT the test date)
VIROTYPE	Character with codes: HIV1: HIV-1 HIV2: HIV-2 HBV: Hepatitis B HCV: Hepatitis C	Type of virus
SEQ_DT	Date - time (for example yyyy-mm-dd hh:mm)	Date and time when the sequencing was performed
LAB	Character	Name of laboratory where the test was performed
TESTTYPE	Numeric with codes: 1 = Genotype 1.1=Genotype done for clinical assessment 1.2=Genotype done for research 2=Phenotype 2.1=Phenotype done for clinical assessment 2.2=Phenotype done for research 3 = Genotype and phenotype 3.1=Genotype and phenotype, done for clinical assessment 3.2=Genotype and phenotype, done for research	Type of test
KIT	Character	Vendor and version/name of the kit used for the test
SOFTWARE	Character	Software and version used to determine resistance
LIBRARY	Character	Library/algorithm used to identify resistance mutations
REFSEQ	Character	Name/identifier of reference HIV strain used to find mutations
SUBTYPE	Character: HIV: A, B, CRF01_AE...etc and mixtures of these if relevant HCV: 1, 2, 3...a, b, c etc and mixtures of these if relevant	Subtype of virus

Example:

PATIENT	SAMP_ID	SAMPLE_D	VIROTYPE	SEQ_DT	LAB	TESTTYPE
AAA	1	2002-12-01	HIV1	2003-12-07	LAB 1	1
AAA	2	2004-01-14	HIV1	2004-01-16	LAB B	1
999	3	2006-05-13	HIV1	2006-05-27 12:14	LAB Z	2
1111	4	2007-06-17	HIV1	2007-06-23	LAB Y	1

KIT	SOFTWARE	LIBRARY	REFSEQ	SUBTYPE
VisibleGenetics			HXB2	CRF_AE
VisibleGenetics			HXB2	CRF_AE
PhenoSense			NL4-3	C
In house	Stanford HIVdb	4.3.6	HXB2	B

12.1.13. Nucleotide sequences (PRO, RT, GP41, GP120) (LAB_RES_LVL_1 file)

Table 13 below details the information to be included in LAB_RES_LVL_1 file (no entry if the test was a phenotype test).

Projects: CHAIN

Table 13 - Variables to be included in LAB_RES_LVL_1 file

Name	Format and definition	Description
SAMP_ID	Character (or numeric if possible)	The assigned UNIQUE sample ID
SEQTYPE	Character with codes: PRO = HIV PRO sequence RT = HIV RT sequence GP41 = HIV GP41 sequence GP120 = HIV GP120 sequence	Type of nucleotide sequence
SEQ_STAR	Numeric	Start position for the sequence
SEQ_STOP	Numeric	Stop position for the sequence
SEQ_NUC	Character/String – IUPAC letter codes only	Nucleotide sequence if available

Example:

SAMP_ID	SEQTYPE	SEQ_STAR	SEQ_STOP	SEQ_NUC
1	PRO	10	99	CCTCAGAT.....
1	RT	112	741	TGTACAGT....

12.1.14. Level 2 amino acid mutations (LAB_RES_LVL_2 file)

Table 14 below details the information to be included in LAB_RES_LVL_2 file (no entry if the test was a phenotype test or sequence has been reported in LAB_RES_LVL_1).

Projects: CHAIN

Table 14 - Variables to be included in LAB_RES_LVL_2 file

Name	Format and definition	Description
SAMP_ID	Character (or numeric if possible)	The assigned UNIQUE sample ID
GENE	Character with codes: PRO = HIV PRO sequence RT = HIV RT sequence GP41 = HIV GP41 sequence GP120 = HIV GP120 sequence	Type of sequence/gene (PRO, RT, GP41, GP120)
AA_POS	Numeric	Position of the mutation in the sequence
AA_POS_SUB	Character a, b, c etc	Subposition used to code insertions
AA_FOUND_1	Amino acid 1-letter code	Mutation (Amino acid) found in the sequence
AA_FOUND_2	Amino acid 1-letter code	Mutation (Amino acid) found in the sequence (if more than 1)
AA_FOUND_3	Amino acid 1-letter code	Mutation (Amino acid) found in the sequence (if more than 2)
AA_FOUND_4	Amino acid 1-letter code	Mutation (Amino acid) found in the sequence (if more than 3)

Example:

SAMP_ID	GENE	AA_POS	AA_POS_S UB	AA_FOUND _1	AA_FOUND _2	AA_FOUND _3	AA_FOUND _4
2	PRO	10		W			
2	RT	69	a	T			
2	RT	69	b	S			
2	RT	69	c	S			
2	RT	184		I	V		